

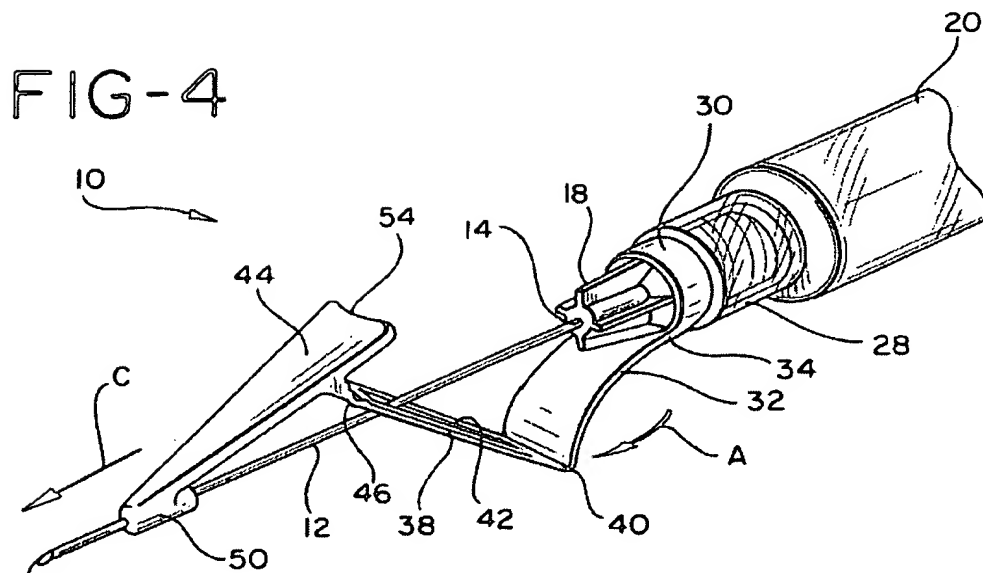
REMARKS

This application has been reviewed in light of the Office Action dated August 12, 2003. Claims 1-93 are pending in the application. Claims 21, 22, 24, 26, 32-59, 61, 66-68, 73-90 and 93 are withdrawn from consideration. Claims 1-4 and 72 are amended in a manner that Applicants believe overcome the rejections in the Office Action. Support for the amendments can be found throughout the specification and figures of the present disclosure and recite aspects of the disclosure that Applicants are believed to be entitled. No new matter or issues are believed to be introduced by the amendments. Claims 91 and 92 are cancelled without prejudice. Applicants reserve the right to prosecute the subject matter of any cancelled claims in continuing applications.

Applicants gratefully acknowledge the allowability of the subject matter recited in claims 3-9, 11, 14-20, 23, 25, 27-31, 60, 62-65 and 69-71. Applicants, however, respectfully submit that in view of the amendments and remarks herein, all claims presently pending in the application are allowable over the art of record.

In the Office Action, claims 1-2, 72 and 91-92 were rejected under 35 U.S.C. §103(a) over U.S. Patent No. 5,925,020 to Nestell (Nestell '020). However, it is respectfully submitted that independent claim 1, claim 2 depending therefrom, and independent claim 72, as amended, clearly and patentably distinguish over the Nestell '020 patent. Claims 91 and 92 are cancelled without prejudice.

In the Office Action, it is initially asserted that "Nestell discloses...a monolithic needle hub including a collar..." however, this is incorrect. Needle hub 18 disclosed by the Nestell '020 patent does not have a collar. In fact, it is syringe 20 of the Nestell '020 patent that includes collar 28 for attachment to hub 18. (col. 3, lines 7-12; FIG. 4 reproduced below). Hub 18 attached to collar 28 of syringe 20 is structurally distinct from a monolithic needle hub with a collar, as recited in Claims 1 and 72 of the present application.



In contrast, amended independent claim 1 of the present application recites, *inter alia*, “[a] medical needle shield apparatus comprising: a monolithic needle hub, a collar extending distally from the needle hub; and a shield having a proximal end receivable by the collar in an interlocking engagement and including a plurality of hingedly connected segments...” Independent claim 72, as amended, recites *inter alia*, “...a needle hub; a collar extending distally from the needle hub...a shield including a proximal end, a distal end and having at least one hinge, the proximal end of the shield being receivable by the collar in an interlocking engagement...”

Further, although the Examiner acknowledges that “Nestell...fails to include...the shield (30) and the collar being in interlocking engagement,” the Examiner continues to allege that “it would have been obvious to rearrange the locking mechanism to be between the proximal end of the shield (30) and the collar portion of the needle hub [which has no collar]...[and] would provide a safety mechanism to prevent the central hub from being removed from the syringe...” This conclusion, however, is misplaced and ignores the applicability of Applicants’ disclosure to various medical needle shield apparatus, such as, for example, fluid collection devices, catheters, etc., as well as syringes.

Moreover, some of the elements and advantages of the present application are overlooked, as recited in amended independent claims 1 and 72, which patentably distinguish over the prior art and cannot be achieved by "rearranging parts." To clarify these distinctions, independent claims 1 and 72 are amended to recite a medical needle shield apparatus that includes a needle hub including a collar extending distally from the needle hub. Some of the advantages of having the collar extend distally from the hub include, for example, convenient and safe manipulation, facile attachment between shield and hub, applicability to various medical needle shield apparatus, etc.

Therefore, the Nestell '020 patent in no way discloses or suggests a structural configuration as recited in amended claims 1 and 72. The Nestell '020 patent does not disclose, *inter alia*, a needle hub including a collar extending distally from the needle hub and a shield having a proximal end receivable by the collar in an interlocking engagement. Because of the above distinctions, it is respectfully submitted that independent claim 1, claim 2 depending therefrom and independent claim 72 patentably distinguish and are not obvious over the Nestell '020 patent. Reconsideration and withdrawal of the rejections are respectfully requested.

In view of the foregoing amendments and remarks, it is respectfully submitted that Claims 1-9, 11, 14-20, 23, 25, 27-31, 60, 62-65, 69 and 70-72 presently pending in the application are believed to be in condition for allowance and patentably distinguish over the art of record. An early notice thereof is earnestly solicited.

If the Examiner should have any questions concerning this communication or feels that an interview would be helpful, the Examiner is requested to call the Applicants' undersigned attorney.

Please charge any deficiency as well as any other fees that may become due at any time during the pendency of this application, or credit any over payment of such fees to deposit account no. 50-0369. Also, in the event that any extensions of time for responding are required for the pending application, please treat this paper as a petition to extend the time as required and charge deposit account no. 50-0369 therefor.

Respectfully submitted,

Dated: January 9, 2004

By: 

Peter B. Sorell, Reg. No. 41,433

Attorney for Applicants

Customer No. 21710

Brown Rudnick Berlack Israels LLP

One Financial Center, Floor 18, Box IP

Boston, MA 02111

Tel.: 617-856-8374

Fax: 617-856-8201